

**UNITED STATES DEPARTMENT OF COMMERCE****United States Patent and Trademark Office**

Address: COMMISSIONER OF PATENTS AND TRADEMARKS  
Washington, D.C. 20231

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/437,449	11/10/99	KUMAR	V P04176US0

EDMUND J SEASE  
ZARLEY MCKEE THOMTE VOORHEES & SEASE  
801 GRAND AVENUE SUITE 3200  
DES MOINES IA 50309

HM12/0709

EXAMINER

KULKOSKY, P

ART UNIT	PAPER NUMBER
1615	9

**DATE MAILED:**

07/09/01

**Please find below and/or attached an Office communication concerning this application or proceeding.**

**Commissioner of Patents and Trademarks**

## Office Action Summary

Application No.	09/937449	Applicant(s)	VISAY KUMAR
Examiner	J. KULFOSKY	Group Art Unit	1615

—The MAILING DATE of this communication appears on the cover sheet beneath the correspondence address—

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE THREE MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, such period shall, by default, expire SIX (6) MONTHS from the mailing date of this communication .
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).

### Status

Responsive to communication(s) filed on APRIL 05, 2001.

This action is FINAL.

Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

### Disposition of Claims

Claim(s) 1, 2, 4-9, 11-14, 16, 19, 21-34 is/are pending in the application.

Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.

Claim(s) \_\_\_\_\_ is/are allowed.

Claim(s) 1, 2, 4-9, 11-14, 16, 19, 21-34 is/are rejected.

Claim(s) \_\_\_\_\_ is/are objected to.

Claim(s) \_\_\_\_\_ are subject to restriction or election requirement.

### Application Papers

- See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.
- The proposed drawing correction, filed on \_\_\_\_\_ is  approved  disapproved.
- The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.
- The specification is objected to by the Examiner.
- The oath or declaration is objected to by the Examiner.

### Priority under 35 U.S.C. § 119 (a)-(d)

Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

- All  Some\*  None of the CERTIFIED copies of the priority documents have been received.
- received in Application No. (Series Code/Serial Number) \_\_\_\_\_.
- received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\*Certified copies not received: \_\_\_\_\_.

### Attachment(s)

<input checked="" type="checkbox"/> Information Disclosure Statement(s), PTO-1449, Paper No(s). _____	<input type="checkbox"/> Interview Summary, PTO-413
<input checked="" type="checkbox"/> Notice of Reference(s) Cited, PTO-892	<input type="checkbox"/> Notice of Informal Patent Application, PTO-152
<input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review, PTO-948	<input type="checkbox"/> Other _____

## Office Action Summary

Art Unit:

1. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1,2,4-9,11-14,16,19,21-34 are rejected under 35 USC 112, par. 1.

The combination of PVAP-PVP is considered to be disclosed as possessing a definite physical structure, such as represented by the data given in the figures, Tables and Declaration of Dr. Vijay Kumar. However, a mere mixture of these art-recognized materials (i.e. both have well-known commercially described properties) is encompassed in the "polymer-entrapped drug" of the instant claims). Pages 20 - 30 of the specification indicate that the physical properties are critical to describing the advantages of the combination of PVAP-PVP in a complex which can only be designated by terms in the claims expressing the complex structure (i.e. the limitations of claim 31,34 and characterizations such as by FT-IR at pages 26-28). It is suggested that the complex of the claims should be further limited so as to express the unique physical structure of the PVAP\_PVP complex which has been prepared in the instant specification.

Art Unit:

1. Claims 19, 21 - 30, 32 are rejected under 35 U.S.C. 103(a) as being unpatentable over Prior Art as cited in the previous action.
2. A free carboxylic group containing polymer and drug PVP complex of the claims may be equivalent to the drug complexes of the references as the same chemical formula types of polymers and drugs are used.

The claims are not limited to complexes of different physical structure and properties than are possessed by compositions of the cited Prior Art wherein a carboxylic copolymer entraps an active agent such as ibuprofen. Release properties of the entrapped drug complexes of the instant claims may be the same as these properties are found in the cited Prior Art.

A different physical structure or working property description has not been demonstrated in comparison with close examples of polymer drug release complexes of the references.

This action is made Final..



PETER F. KULKOSKY  
PRIMARY EXAMINER